NEW YORK
LONDON
SINGAPORE
PHILADELPHIA
CHICAGO
WASHINGTON, DC
SAN FRANCISCO
SILICON VALLEY
SAN DIEGO
LOS ANGELES
TAIWAN
BOSTON
HOUSTON
AUSTIN
HANOI
HO CHI MINH CITY

DuaneMorris®

FIRM and AFFILIATE OFFICES

SETH A. GOLDBERG
DIRECT DIAL: +1 215 979 1175
PERSONAL FAX: +1 215 689 2198
E-MAIL: SAGoldberg@duanemorris.com

www.duanemorris.com

SHANGHAI
ATLANTA
BALTIMORE
WILMINGTON
MIAMI
BOCA RATON
PITTSBURGH
NEWARK
LAS VEGAS
CHERRY HILL
LAKE TAHOE
MYANMAR
OMAN
A GCC REPRESENTATIVE OFFICE OF DUANE MORRIS

ALLIANCES IN MEXICO
AND SRI LANKA

November 5, 2019

VIA ECF

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, NJ 08101

Re: In re Valsartan NDMA Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

Pursuant to the Court's October 22, 2019 Order (Dkt. 280), the Manufacturing Defendants[1] submit this letter brief in support of their positions on the following "macro" discovery issues: (1) the extent of discovery regarding foreign regulatory materials and communications; (2) the extent of discovery regarding foreign sales, marketing, and agreements; (3) the extent of discovery regarding each applicable defendant's finished dose manufacturing process; (4) the extent of discovery regarding valsartan testing; (5) whether health risk discovery should be limited to the injuries alleged in the master and other complaints; (6) the relevant time period for the custodial search and production of responsive documents as to each defendant; (7) the type, nature, scope

[1] The positions expressed in this letter are those of the Manufacturing Defendants to whom the Plaintiffs' discovery requests have been directed. Because the retailers (the "Retailer Defendants") and the wholesaler/distributor/repackaging defendants (the "Wholesaler/Distributor/Repackaging Defendants") have not been involved in the meet and confers relating to these issues, and consistent with the Court's assurance that the issues raised during the current discussion of macro discovery issues need not be exclusive or dispositive to macro issues that may arise later in the proceedings as discovery proceeds, the Retailer Defendants and the Wholesaler/Distributor/Repackaging Defendants reserve the right to comment at a later date on these issues.

and time frame of the privilege logs to be produced; and (8) the cost and mechanics of the translation of defendants' foreign documents.

I. PRELIMINARY STATEMENT

Although there are three Master Complaints asserted against over 45 defendants and counting, the core dispute in this case is straightforward: Plaintiffs allege that the manufacturing process for valsartan active pharmaceutical ingredient ("API") caused the valsartan drugs at issue to contain NDMA or NDEA at levels Plaintiffs contend cause cancer. The purpose of this litigation is to determine when, how, and why the alleged impurities occurred, the potential concentration of NDMA or NDEA in the tablets that each Plaintiff took, and whether NDMA or NDEA at that level harmed the Plaintiff.

Plaintiffs' approach to discovery strays far afield from these core issues. Plaintiffs have served 122 document requests on the Manufacturing Defendants,[2] many of which contain between 5 and 25 sub-requests; they have argued that custodian lists should include *every* employee who has had *any* involvement with valsartan, from the employees who placed labels on drums of API up to a CEO; and they have proposed over 400 search terms and modifiers. They request documents related to various types of testing, when only certain types of chromatography are capable of detecting NDMA or NDEA. They request *all* documents related to the finished dose manufacturing process, when there is no allegation that this process had any effect on the presence of NDMA or NDEA in valsartan. They request documents related to "risk assessment, "safety," "evaluation," and "health risks," without defining those terms or limiting them to the injuries alleged in this litigation. And they request documents related to communications with *every* foreign and domestic regulatory agency and to sales and marketing in *any* market, when each Plaintiff purchased and consumed valsartan in the United States.

In short, Plaintiffs' unbounded and far-reaching discovery requests fly in the face of this Court's repeated reminder that this MDL should not "get sidetracked by extraneous issues" or "unsupportable claims." Aug. 14, 2019 Letter from Judge Kugler (Dkt. 183); *see also* July 10, 2019 Tr. at 22 (reiterating that court's goal "to get to the crux of the merits and not be distracted by tangential issues" is a "general theme[]" that "cut[s] across every single avenue of this case"); April 10, 2019 Tr. at 31:15-17 (stating that one purpose of core discovery is to "guide your discovery in the case so you don't go down a rabbit hole"). But Plaintiffs' broad requests do just that; they request every document related to valsartan marketed anywhere in the world at any point in the last decade. Such broad requests serve only to overly burden the Defendants and to create opportunities for distraction and delay. To ensure the just and speedy resolution of these cases, the

[2] Plaintiffs' First Set of Requests for Production of Documents to All API and Finished-Dose Manufacturing Defendants is attached hereto as Exhibit A.

Court should appropriately tailor discovery to the facts and issues that actually matter to "the crux of the merits." July 10, 2019 Tr. at 22.

II. LEGAL STANDARD

Through recent amendment, Rule 26(b) provides for the discovery of non-privileged information relevant to "any party's claim or defense," whereas it previously permitted discovery of non-privileged information relevant to "the subject matter involved in the pending action." Fed. R. Civ. P. 26(b)(1). "This change in Rule 26 indicates that the scope of discovery has been narrowed … and that relevance is more closely tied to the actual allegations contained in the complaint." *Beauchem v. Rockford Products Corp.*, No. 01-50134, 2002 WL 100405, at *1 (N.D. Ill. Jan. 24, 2002). *See also Engers v. AT&T*, No. 98-3660, 2004 WL 5902865, at *7 (D.N.J. March 9, 2004) ("[T]he language of permissible inquiry w[as] narrowed to allow discovery only on matters 'relevant to the *claim* or *defense* of any party.'" (emphasis in original)); *Sanyo Laser Products, Inc. v. Arista Records, Inc.*, 214 F.R.D. 496, 497 (S.D. Ind. 2003). After this amendment, parties "have no entitlement to discovery to develop new claims or defenses that are not already identified in the pleadings." *Engers*, 2004 WL 5902856, at *7 (quoting *Court Rules: Amendments to Fed.R.Civ.P.*, 192 F.R.D. 340, 389 (2000)).

"Although the scope of discovery under the Federal Rules is broad, this right is not unlimited and may be circumscribed." *Bayer AG v. Betachem, Inc.*, 173 F.3d 188, 191 (3d Cir. 1999). Discovery must also be "proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1). "The purpose of this rule of proportionality is to guard against redundant or disproportionate discovery." *Ramirez v. World Mission Soc'y Church of God*, No. 14-1708, 2019 WL 1569819, at *3 (D.N.J. April 10. 2019) (quoting *Takacs v. Union Cty.*, No. 08-711, 2009 WL 3048471, at *1 (D.N.J. Sept. 23, 2009)). "[W]hen a request for discovery is overly broad on its face or when relevancy is not readily apparent, the party seeking discovery has the burden to show the relevancy of the request." *Burleson v. Cooper Tire & Rubber Co.*, 2014 WL 11514677, at *1 (D.N.M. June 12, 2014) (quoting *Bonanno v. Quizno's Franchise Co.*, 255 F.R.D. 550, 553 (D. Colo. 2009)); *accord Gregory v. Gregory*, No. 15-0320, 2016 WL 6122456, at *3 (D.N.J. Oct. 18, 2016); *Engers*, 2004 WL 5902865, at *7.

Courts require that a plaintiff make a "threshold showing of relevance . . . before parties are required to open wide the doors of discovery and to produce a variety of information which does not reasonably bear upon the issues in the case." *Jesberg v. Baxter Healthcare Corp.*, No. 97-1062, 2005 WL 8164570, at *4 (D. Minn. June 24, 2005); *see also In re Santa Fe Nat. Tobacco Co. Mktg. & Sales Practices & Prods. Liab. Litig.*, No. 16-2695, 2018 WL 4200315, at *6 (D.N.M. Aug. 31, 2018) (noting that a "modicum of objective support" is a prerequisite to seeking discovery on a particular subject); *Cordero v. Warren*, No. 12-2136, 2017 WL 2367049, at *1 (D.N.J. May 31, 2017) ("[O]nce a party opposing discovery raises an objection, the party seeking discovery must demonstrate the relevancy of the requested information." (internal citation and punctuation omitted)); *In re New England Compounding Pharmacy, Inc. Prods. Liab. Litig.*, No. 13-2419,

2015 WL 13715287, at *2 (D. Mass. Feb. 26, 2015) ("Parties must disclose some relevant factual basis for their claim before requested discovery will be allowed." (citation omitted)).

III. PERTINENT FACTUAL BACKGROUND

A. Valsartan is the Active Pharmaceutical Ingredient Contained in Safe, Effective, and Life-Saving Heart Medications.

Valsartan is the active pharmaceutical ingredient ("API") contained in medications indicated for the treatment of hypertension, heart failure, and post-myocardial infarction. It is an angiotensin II receptor blocker ("ARB") that operates by relaxing blood vessels, which lowers blood pressure and makes it easier for the heart to pump blood. The Food & Drug Administration ("FDA") first approved a valsartan medication for use under the name brand Diovan® in oral capsule form in 1996, followed by approval in oral tablet form in 2001. By approving Diovan®, the FDA determined that it was safe and effective to treat hypertension, heart failure, and post-myocardial infarctions. In 2012, the FDA approved the first of many applications for a generic pharmaceutical manufacturer to begin marketing more affordable, bioequivalent forms valsartan drugs.[3]

The Defendants in this litigation are various entities involved in bringing valsartan medications to the U.S. market, and fall into six distinct groups–API manufacturers (including API distributors), finished dose manufacturers (including finished dose distributors), third-party distributors, repackagers, retailers, and FDA liaisons. At this time, Plaintiffs have only served Requests for Production of Documents directed to the API manufacturer and finished dose manufacturer defendants. API manufacturers use a combination of processes to create valsartan API. Finished dose manufacturers purchase valsartan API from the API manufacturers and combine it with inactive ingredients and other excipients to create a final product with the desired quantity of valsartan API in a deliverable form.

B. The Valsartan Recall

On July 13, 2018, Prinston Pharmaceutical Inc., Solco Healthcare, Teva Pharmaceuticals USA, Inc., and Major Pharmaceuticals (a distributor of valsartan supplied by Teva Pharmaceuticals and labeled as Major Pharmaceuticals) issued voluntary recalls of various lots of valsartan after receiving information that the valsartan API manufactured by Zhejiang Huahai Pharmaceutical ("ZHP") in Linhai, China contained trace amounts of N-nitrosodimethylamine ("NDMA"). The FDA published an announcement of these voluntary recalls, and in the ensuing

[3] Other branded medications containing valsartan API include Diovan HCT (hydrochlorothiazide; valsartan), Exforge (amlodipine besylate; valsartan); and Exforge HCT (amlodipine besylate; hydrochlorothiazide; valsartan). The FDA has approved generic versions of each of these drugs for sale.

months these recalls have expanded to include additional lots and to involve the products of other Defendants. Certain pharmaceutical companies recalled additional lots of valsartan tablets because they were suspected of containing trace amounts of N-nitrosodiethylamine ("NDEA"), another nitrosamine, which has similar characteristics and composition as NDMA.

These recalls resulted in an extensive investigation by the FDA and the affected manufacturers, seeking to identify API manufacturing processes that may result in the presence of NDMA and/or NDEA in valsartan API. Although the NDMA and NDEA in certain lots of valsartan API appeared to have exceeded acceptable levels, giving rise to the voluntary recalls, the FDA's July 13, 2018 announcement stated: "Because valsartan is used in medicines to treat serious medical conditions, patients taking the recalled valsartan-containing medicines should continue taking their medicine until they have a replacement product." The FDA advised patients to contact their health care professional if their medication was included in the recall and to discuss using an alternative product or treatment option rather than ceasing to take patients' currently prescribed valsartan medications.[4] Additionally, the FDA concluded that any increased risk of cancer for those ingesting valsartan medications with NDMA or NDEA is quite small. Specifically, the FDA concluded that assuming patients took valsartan at the highest dose (320 mg) containing NDMA or NDEA daily for four years, for those taking medication containing NDMA 1 in 8,000 of those patients would see an additional case of cancer, and for those taking medication containing NDEA, 1 in 18,000 would see an additional case of cancer.[5] The FDA further recognized that many patients who took valsartan took it at lower doses, and that "their risks would be less." *Id*.

C. The Master Complaints

Plaintiffs have filed three Master Complaints in this MDL, bringing personal injury, economic loss, and medical monitoring claims. Specifically, Plaintiffs allege that the valsartan they purchased and/or consumed caused them injury because the valsartan products contained NDMA and/or NDEA impurities resulting from a specific step in the valsartan API manufacturing process. *See, e.g.,* Personal Injury Master Complaint (Dkt. 122) ¶ 167; Economic Loss Master Complaint (Dkt. 121) ¶ 327; Medical Monitoring Master Complaint (Dkt. 123) ¶ 289 (alleging that NDMA and NDEA are byproducts of the chemical reaction involving the solvent used to create the tetrazole ring found in Valsartan).

The Personal Injury Plaintiffs allege that the specific injury they suffered was cancer. *See* Personal Injury Master Complaint at ¶ 394 ("As a result of Plaintiffs' ingestion of the VCDs,

---

[4] Available at: https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity (last visited Nov. 3, 2019).

[5] Available at: https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products (last visited Nov. 4, 2019).

Plaintiffs developed and were diagnosed with cancer, which caused permanent and disabling injuries and/or death."). In the Short Form Complaints filed to date, Personal Injury Plaintiffs overwhelmingly identify certain cancers as their alleged injuries. Similarly, the Economic Loss Master Complaint alleges that Plaintiffs overpaid for valsartan because NDMA and NDEA have the potential to increase the risk of cancer, Dkt. 121 ¶¶ 306-25, 363, and the Medical Monitoring Plaintiffs seek compensation for alleged cellular and genetic injury that increases their risk of cancer, Dkt. 123 ¶¶ 1, 10-19.

IV. "MACRO" DISCOVERY ISSUES

A. Discovery of Regulatory Materials and Communications Should Be Limited to Information Relating to the FDA.

1. Facts Pertinent to This Argument

"This litigation arises out of an investigation by the U.S. Food and Drug Administration into impurities found in generic drug products containing valsartan[.]" Transfer Order (Dkt. 1) at 1. "All actions stem from the same FDA investigation and voluntary recall announced in July 2018." *Id.* at 2. Indeed, not a single Plaintiff's claims relate to or arise from the purchase or use of valsartan medications outside of the United States. Because the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations represent the exclusive sources of authority regarding the formulation, manufacture, marketing, and recalls of the valsartan medications at issue in this litigation, the only regulatory materials germane to this MDL are those relating to the FDA. And, as the Court is well aware, FDA remains on the cutting edge of the ongoing efforts to ensure its "strict standards for safety, effectiveness and quality" are met. August 28, 2019 FDA Statement.[6]

2. Example Discovery Requests

REQUEST NO. 52: *Produce all regulatory documentation and communications with regard to contamination or recalls of valsartan.*

REQUEST NO. 53: *Produce all regulatory documentation and communications with regard to any aspect of the manufacturing process for valsartan.*

REQUEST NO. 54: *Produce transcripts, notes, memoranda, or other documentation of any hearings or other proceedings or meetings which took place at or with any regulatory agency relating to the actual and/or potential contamination or recall of valsartan.*

---

[6] Available at: https://www.fda.gov/news-events/press-announcements/statement-agencys-ongoing-efforts-resolve-safety-issue-arb-medications (last visited Nov. 1, 2019).

See also Requests No. 4(8), 5(8), 6(8), 8, 10(8), 13, 42-43, 51, 57, 59-62, 64-68, 72-74, 77-78, and 107(aa).

3. Argument and Citations to Authority

There is no justification for Plaintiffs' grasping attempt to expand discovery to foreign regulatory bodies. In pursuing discovery, a party is not allowed "to roam in shadow zones of relevancy[.]" *In re Fontaine*, 402 F. Supp. 1219, 1221 (E.D.N.Y. 1975). "Discovery is not intended as a fishing expedition[.] [T]he plaintiff must have some basis in fact for the action." *Claude P. Bamberger Int'l, Inc. v. Rohm & Haas Co.*, No. 96-1041, 1998 WL 684263, at *2 (D.N.J. Apr. 1, 1998) (citation and alteration omitted); *accord Hashem v. Hunterdon Cty.*, No. 15-8585, 2017 WL 2215122, at * (D.N.J. May 18, 2017) ("However, while the scope of discovery is broad, it is not unlimited and should not serve as a fishing expedition." (internal citation and punctuation omitted)).

In this MDL, Plaintiffs are not flying blind. The manufacturer Defendants have produced hundreds of thousands of pages of materials, including ANDA files, Drug Master Files, and FDA correspondence concerning the recalls. One of the primary justifications for the core discovery process was to arm Plaintiffs with information so as to narrow merits discovery and avoid fishing expeditions. *See* April 10, 2019 Tr. at 31:15-17 (stating that one purpose of core discovery is to "guide your discovery in the case so you don't go down a rabbit hole"). FDA is the regulatory body that approved Defendants' valsartan medications; FDA is the regulatory body that promulgates the rules and regulations governing Plaintiffs' medications; and FDA is the regulatory body overseeing the relevant recalls and related investigation. FDA is therefore the only relevant regulatory agency for purposes of the MDL, and Plaintiffs certainly have not come forward with any predicate facts to suggest otherwise. Because foreign regulatory evidence is not relevant, it is not discoverable. *See In re Bard IVC Filters Prod. Liab. Litig.*, 317 F.R.D. 562, 564 (D. Ariz. 2016) (noting that Rule 26 was amended in 2015 to dispel the incorrect notion that the phrase "reasonably calculated to lead to the discovery of admissible evidence" defined the scope of discovery and emphasizing, instead, that "[t]he test going forward" is whether requested information is both relevant and proportionate to the needs of the case).

In fact, numerous courts have ruled that, in litigation involving medications manufactured for the U.S. market, documents concerning regulatory bodies *other than* FDA are irrelevant. *See In re Seroquel Prod. Liab. Litig.*, No. 06-1769, 2009 WL 223140, at *6 (M.D. Fla. Jan. 30, 2009), *aff'd*, 601 F. Supp. 2d 1313 (M.D. Fla. 2009) ("[F]oreign regulatory actions have no relevance to Plaintiff's main case."); *Pa. Tr. Co. v. Dorel Juvenile Grp., Inc.*, 851 F. Supp. 2d 831, 842-43 (E.D. Pa. 2011) (granting defendant's motion to exclude evidence of foreign regulatory actions and labeling requirements and stating that plaintiff failed to demonstrate how "[defendant's] obligations under [foreign] law are relevant here"); *In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 950, 965-66 (D. Minn. 2009) (finding foreign regulatory actions irrelevant to U.S.-based litigation); *Deviner v. Electrolux Motor, AB*, 844 F.2d 769, 771 n.2, 773 (11th Cir. 1988) (affirming

exclusion of foreign regulatory requirements for chain saws because foreign "[s]tandards are not relevant in a U.S. product liability case").

In contrast, decisions finding foreign regulatory evidence to be relevant either predate the 2015 Amendment to Rule 26 or were based on the rationale that such information might shed light the defendant's notice or knowledge. However, as the mountain of core discovery makes clear, Defendants had no notice or knowledge of nitrosamine contamination before the summer of 2018 when FDA developed novel testing methods to detect impurities at the levels observed in Defendants' valsartan medications. *See* January 25, 2019 FDA Statement ("One challenge we've faced is that NDMA's properties make it hard to detect in standard laboratory testing – the kind of testing results that are reviewed during a surveillance inspection. In St. Louis, the FDA maintains one of the most advanced pharmaceutical laboratories of any regulatory agency in the world . . . . [FDA's] scientists have developed and refined novel and sophisticated testing methods specifically designed to detect and quantify the NDMA and NDEA in all ARB medicines.").[7]

Moreover, Defendants have authorized FDA to share information regarding the testing, recalls, and investigation of valsartan API with other foreign regulators, thereby ensuring that the information conveyed to regulators is consistent across the board. *See, e.g.*, MYLAN-MDL2875-00029944; *see also In re Bard*, 317 F.R.D. at 566 (finding foreign regulatory documents to be, at most, "marginally relevant" to "determine if any of those communications have been inconsistent with Defendants' communications with American regulators"). Furthermore—given that valsartan has been recalled from markets around the world starting in July 2018—there is no reason to believe that any Defendant disclosed a risk of NDMA or NDEA to a foreign regulatory body, but not the FDA, before the 2018 recalls.[8] It is "mere conjecture that communications between . . . foreign regulators might be inconsistent with Defendants' communications with American regulators . . .—more hope than likelihood." *Id.*

And yet, even if Plaintiffs could hypothesize some scenario where foreign regulatory materials might be relevant, these requests are unduly burdensome and "overly broad on [their] face[.]" *Burleson*, 2014 WL 11514677, at *1. Indeed, insofar as Plaintiffs demand production of "all communications" with foreign regulatory agencies located all over the world, dating back at least 10 years, related to *any* aspect of the manufacturing process, the burden for Defendants to comply would be "substantial." *In re Bard*, 317 F.R.D. at 566. As made clear in their objections to Plaintiffs' first set of document requests, Defendants are willing to meet and confer with respect

[7] Available at: https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-and-arb-class-impurities-and-agencys-steps (last visited Nov. 1, 2019).

[8] *See* Jen Christensen, *Common Heart Drug Recalled in 22 Countries for Possible Cancer Link*, accessible at: https://www.cnn.com/2018/07/06/health/valsartan-heart-drug-recall-intl/index.html (last visited Nov. 3, 2019).

to Plaintiffs' requests for regulatory documents. But, as drafted, these requests are clearly beyond the scope of permissible discovery.

B. Discovery of Sales, Marketing Materials, and Agreements Should be Limited to Materials Related to Sales of Valsartan API Linked to the U.S. Market.

1. Facts Pertinent to This Argument

Valsartan API is supplied to over 250 customers in around 70 countries. In this MDL, *not one* Plaintiff's claims relate to or arise from the purchase or use of valsartan medications outside of the United States. Accordingly, discovery should be limited to sales, marketing materials, and Agreements involving customers authorized to market valsartan in the United States.

2. Example Discovery Requests

REQUEST NO. 6: *Produce all formal and informal agreements, contracts, or licenses that the answering defendant is a party to, with regard to (1) manufacture, (2) testing, (3) purity and contamination, (4) quality assurance, (5) risk assessment, (6) medical and clinical assessments, (7) safety, (8) communications with regulatory agencies, (9) formulation, (10) production, (11) distribution, (12) packaging, (13) evaluation, (14) sale, (15) marketing, (16) communications with private individuals or entities, and (17) procurement, with regard to valsartan and/or its ingredients.*

REQUEST NO. 80: *Documents sufficient to show all (past and present) labels and packaging materials, including all associated documentation and disclosures provided to medical professionals, purchasers, including TPPs, consumers, wholesale distributors, retail pharmacies, and other direct and indirect purchasers of valsartan, for each NDC, Batch Number, and Lot Number of valsartan sold in the United States from January 1, 2010 to the present, including copies and drafts of all such materials, and documents sufficient to show the time period during which each exemplar was in use.*

REQUEST NO. 81: *All advertisements, and sales and marketing material for valsartan utilized from January 1, 2010 to the present, and charts setting forth the approval date, in use dates, and medium (i.e. website, sales document, marketing brochure).*

REQUEST NO. 105: *Produce all documents relating to any arrangements between you and any other person or entity that did, could, or may affect the quantity or price of valsartan purchased, including but not limited to rebate agreements.*

See also Requests No. 5(15), 10(15), 31, 69-71, 73, 76, 79, 82-89, 93-98, 103-105, 107(a)-(i), 107(1)-(ii), 108-110, and 111.

3. Argument and Citations to Authority

In addition to being overbroad, Plaintiffs fail to offer any predicate showing that foreign sales, marketing materials, and agreements are relevant to their state-law claims. The analysis in Section A, *supra*, relating to fishing expeditions, applies with equal force to these requests. Plaintiffs do not claim to have been prescribed, purchased, or used valsartan medications in any country other than United States.

Furthermore, there is no suggestion that Plaintiffs' physicians considered or relied upon any foreign marketing materials or any marketing materials related to sales of API—even assuming such materials exist. *See New York v. Actavis, PLC*, No. 14-7473, 2014 WL 7015198, at *27 (S.D.N.Y. Dec. 11, 2014) *aff'd sub nom. New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) (observing that, as a result of marketplace realities, "[g]eneric products are typically not marketed to physicians or patients"). As such, the only sales, marketing, and agreements even potentially relevant to this litigation are those concerning finished dose sold in the U.S. market. *See In re Norplant Contraceptive Prods. Liab. Litig.*, MDL No. 1038, 1997 WL 81092, at *1 (E.D. Tex. Feb. 21, 1997) (holding that "[a]bsent evidence that the [plaintiffs'] physicians were exposed" to them, "promotional and advertising materials are not relevant evidence"). And, suffice it to say, any foreign-based conduct cannot form the basis of a punitive-damages claim, so, again, evidence concerning foreign sales and marketing have no bearing on this litigation. *See State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) (noting that, as a "general rule," a state does not have "a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction"); *Johansen v. Combustion Eng'g, Inc.*, 170 F.3d 1320, 1333 (11th Cir. 1999) ("The Supreme Court has instructed that punitive damages must be based upon conduct in a single state—the state where the tortious conduct occurred—and reflect a legitimate state interest in punishing and deterring that conduct."); *In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 613 (7th Cir. 1997), *abrogated on other grounds by Rivet v. Regions Bank of Louisiana*, 522 U.S. 470 (1998) ("A state cannot regulate sales that take place wholly outside it.").

Discovery related to API sales should therefore be limited to sales to companies authorized to market valsartan medications in the United States, i.e., holders of approved ANDAs; and discovery related to finished dose sales should be limited to finished dose sales within the United States.

C. Discovery Regarding Manufacturing Should Be Limited to the API Manufacturing Process.

1. Facts Pertinent to This Argument

Plaintiffs' Personal Injury Master Complaint alleges:

> [T]he reason Defendants' manufacturing process produced [NDMA and NDEA] is linked to the tetrazole group that most ARB drugs have. Solvents used to produce the tetrazole ring, such as N-Dimethylformamide (DMF), can result in the formation of drug impurities or new active ingredients, such as NDMA and NDEA, as a byproduct of the chemical reactions.

Dkt. 122 ¶ 167.

The use of solvents to produce a tetrazole ring occurs during the API manufacturing process for valsartan. Plaintiffs further allege that the presence of these impurities is due to API manufacturing process change which occurred on or around 2012. *Id.* ¶¶ 169, 190. Plaintiffs repeatedly note that the impurities at issue are found in valsartan API. *See, e.g.*, *id.* ¶¶ 170, 171, 174.

Finished dose manufacturers purchase valsartan API from the API manufacturers and combine it with inactive ingredients and other excipients to create a final product with the desired quantity of valsartan API in a deliverable form. Plaintiffs' Master Complaints make no allegations specific to the finished dose manufacturing process. *See generally* Dkt. 121, 122 & 123. Throughout these extensive filings, Plaintiffs do not identify any process or step which takes place at the finished dose manufacturing level that could conceivably cause the impurities at issue in this litigation to arise. To date, Defendants are not aware of any public statements by the FDA or any other regulatory authority which implicate the finished dose manufacturing process in the presence of impurities in valsartan-containing products.

2. Example Discovery Requests

> REQUEST NO 22: *Produce all documents setting forth the manufacturing/fabrication/production process for the finished drug formulation of valsartan sold by you or any of your affiliated entities, including any quality assurance and testing, and any modifications thereto.*

> REQUEST NO 23: *Produce all documents identifying any patented device, machine, or technology utilized in the manufacture or testing of valsartan.*

> REQUEST NO 24: *Produce all documents relating to all patents filed by you or employees and/or agents associated with you to any foreign regulatory body regarding any manufacturing processes associated with the creation or manufacturing of valsartan, including all supporting documentation and/or correspondence associated with the filing of those patents.*

See also Requests No. 1(d); 4(1), 4(10), 5(1), 5(10), 6(1), 6(10), 10(1), 10(10), 27-29, 53, 56-57, 65, and 87.

3. Argument and Citations to Authority

Discovery into the finished dose manufacturing process reaches beyond the bounds of Plaintiffs' claims and would be improper, unduly burdensome, and disproportionate to the needs of the case. Discovery into the API manufacturing process allegedly responsible for introducing the impurities is necessary. Similarly, Defendants acknowledge that, to the extent the finished dose manufacturers conducted testing on the API at issue, discovery into this testing and the processes associated therewith may be discoverable under Rule 26. *See* Fed. R. Civ. P. 26(b)(1) ("Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case . . . ."). However, the processes by which the finished dose manufacturers turned the API at issue into finished dose products has not been implicated—either in Plaintiffs' Master Complaints or in any statements issued by the FDA or other regulatory bodies. Discovery into these processes risks distracting the Court and the parties from the significant issues at the heart of this litigation and is not proportional to the needs of the case. *See id.*

Setting aside the potential relevance of specific forms of testing, which is being addressed in Section IV.D of this brief, documentation of the valsartan finished dose manufacturing process and background documentation regarding the machines utilized in this process have—according to Plaintiffs' own factual allegations—no bearing on how impurities allegedly made their way into valsartan-containing products. Allowing discovery on finished dose processes, machines, patents, and technologies would "unreasonably expand the scope of litigation and result in needless satellite litigation." *See Cooper Health Sys. v. Virtua Health, Inc.*, 259 F.R.D. 208, 216 (D.N.J. 2009); *see also id.* ("Plaintiff's hope that the requested reports may contain relevant information does not justify its request."). This is especially true with respect to sensitive patents and technologies which would require substantial review, redaction, and confidentiality designation while contributing nothing to the parties' understanding of the case.

Discovery into Defendants' manufacturing processes promises to be some of the most extensive investigation undertaken in this litigation. Conceivably, if the scope of discovery is not limited, the parties will be forced to engage in the same depth of document collection, review, production, and analysis with respect to both API manufacturing and the manufacturing process at the finished dose level. Equivalent discovery cannot be justified as proportional to the needs of the

case under Rule 26(b)(1) for both the API process at the very heart of Plaintiffs' claims and the finished dose manufacturing process, which has not been implicated in any way. Rule 26 provides that the Court "*must* limit the frequency or extent of discovery . . . if it determines that . . . the proposed discovery is outside the scope permitted by Rule 26(b)(1)." Fed. R. Civ. P. 26(b)(2)(C)(iii) (emphasis added). The Court should do so here.

During meet and confer discussions, Plaintiffs have expressed that discovery into the finished dose manufacturing process is needed to allow Plaintiffs to describe the production of and supply chain for valsartan-containing products to a jury. First, there is nothing conceptually challenging about explaining how finished dose manufacturers purchase valsartan API and combine it with other drugs, inactive ingredients, and other excipients to create a final product with the desired quantity of valsartan API in a deliverable form. Second, Plaintiffs have already received documentation describing the finished dose manufacturing process followed by each Defendant through production of the applicable ANDAs. Third, to the extent copious discovery into the finished dose manufacturing process would provide some minimally relevant information to enhance Plaintiffs' understanding of the case, such information can be obtained from other sources which are more convenient and far less burdensome and expensive. *See* Fed. R. Civ. P. 26(b)(2)(C)(i); *see also Cooper Health Sys.*, 259 F.R.D. at 216 (finding that even if the documents sought by Plaintiff in discovery were minimally relevant, the weighing of factors in former Rule 26(b)(2)(C) resulted in a finding that the reports not be produced).

Accordingly, the scope of discovery into the finished dose manufacturing process can and should be circumscribed. Defendants ask the Court to limit discovery into the finished dose manufacturing process to the testing performed on the API at issue by the finished dose manufacturers. However, Plaintiffs' discovery requests that seek documents or information about the finished dose manufacturers' ingredients, excipients, machines, processes, technologies, patents, and the like—unrelated to testing of the API at issue and beyond the ANDAs already produced—bear no relevance to Plaintiffs' claims and are not proportional to the needs of this litigation. *See* Fed. R. Civ. P. 26(b)(1).

D. Discovery Regarding Testing Should Be Limited to Chromatography Testing for NDMA and NDEA Impurities.

1. Facts Pertinent to This Argument

The universe of tests used to analyze pharmaceutical drug substances and their ingredients is expansive. Within the realm of API testing, manufacturers may perform tests concerning: (1) appearance; (2) solubility; (3) identification; (4) dissolution; (5) presence of water; (6) presence of residue on ignition; (7) presence of heavy metals; (8) presence of certain impurities; (9) presence of specific residual solvents; and (10) assay, for purity and potency. For generic drug finished dose tablets, manufacturers may perform tests evaluating: (1) appearance; (2) identification; (3) assay; (4) dissolution; (5) impurities; (6) uniformity of dosage units; (7) residual solvents; and (8) bioequivalence.

Only a narrow subsection of the laundry list of tests mentioned above is employed to detect the presence of impurities, often conducted using high performance liquid chromatography ("HPLC") or gas chromatography ("GC"). HPLC or GC impurity tests require the designation of certain identified impurities along with correlated specific thresholds representing acceptable levels of concentration. Further, such tests may register certain unidentified peaks along the chromatogram potentially representing "unknown" impurities. Pursuant to guidelines established by the International Conference of Harmonization ("ICH"), for purposes of drug substances used in generic drug products, "unknown" impurities (those not specifically identified by the tester) registering above a concentration of 0.1% should be individually isolated and characterized. *See, e.g.*, FDA: *ANDAs: Impurities in Drug Substances*.[9] Nitrosamine impurities, falling within the category of "unknown" impurities at the time the HPLC impurity tests were run, would have consequently only been identified through isolation and characterized if HPLC or GC tests identified the presence of such impurities at levels exceeding the ICH identification threshold.

2. Example Discovery Requests

Plaintiffs seek broad discovery relating to testing. For example, in their First Set of Requests for Production to All API and Finished Dose Manufacturers, Plaintiffs include the following requests:

> REQUEST NO. 35: *Produce all documents setting forth the planning, occurrence, or results of any testing (including chromatography) of valsartan that had the potential to directly or indirectly identify impurities or contamination.*
>
> REQUEST NO. 38: *Produce all documents or communications with regard to the actual or attempted detection of impurities or contaminants in valsartan or any component or ingredient thereof, including chromatographs, and intermediate testing.*
>
> REQUEST NO. 44: *Produce documents sufficient to show (a) all testing, prior to any recall, of valsartan you manufactured or sourced, (b) all testing, after any recall, of valsartan you manufactured or sourced, (c) results of the foregoing testing; (d) any testing that was considered but not performed before or after any recall, including the reason(s) why such testing was not performed, and (e) to the extent any lot, batch, or other production quantity was not testing for impurities or contamination, complete*

[9] Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/andas-impurities-drug-substances (last visited Nov. 3, 2019).

> *documentation with regard to the reason(s) why no such testing was performed.*

See also Requests No. 4(2), 4(4), 4(13), 5(2), 5(4), 5(13), 6(2), 6(4), 6(13), 10(2), 10(4), 10(13), 21-23, 25, 39-40, 42-43, and 78.

Moreover, the course of the Parties' meet and confer efforts on the "macro" discovery issues, Plaintiffs have requested that Defendants provide exemplar test results of *each and every* test performed on valsartan.

These requests for production, to the extent they would provide Plaintiffs with access to information on testing or attempted detection of items other than impurities such as NDMA or NDEA, are "overly broad on [their] face[.]" *Burleson*, 2014 WL 11514677, at *1. The complaints themselves delineate the relevant bounds of discovery as to documents concerning valsartan testing; based on Plaintiffs' allegations, the only relevant tests are those that would have identified the presence of the nitrosamine impurities identified in the various complaints, namely NDMA and NDEA. *See Beauchem*, 2002 WL 100405, at *1; *Engers*, 2004 WL 5902856, at *7; and *Sanyo Laser Products*, 214 F.R.D. at 497.

3. Argument and Citations to Authority

Based on the impurities alleged in the complaints, Plaintiffs should be entitled to discovery only of the testing documents related to identification of NDMA and NDEA impurities: the impurity tests (HPLC or GC), including those performed as part of stability testing.[10] To permit otherwise would be to allow a fishing expedition upon a lake devoid of fish.

Numerous cases support limiting the scope of testing-oriented discovery in this respect. For instance, in *Stipes v. Stanley*, a plaintiff sued the manufacturer of a pneumatic stick nailer, claiming that the defective product caused an injury, and instituted broad discovery. *See* 691 N.Y.S. 2d 535 (N.Y. App. 1999). There, the court held that "the plaintiff's demand for product test documentation not relating to the operation or function of components of the Stanley-Bostitch N80SB pneumatic stick nailer which allegedly caused the plaintiff's injuries is immaterial, irrelevant, [and] unduly broad[.]" *Id.* at 536. In *Mazda Motor Corp. v. Quinn*, the court held that certain discovery requests—including "'[a]ny and all predictive analyses, studies, tests, investigations, or examinations conducted or prepared during the [time period] which relate to collisions or failure modes involving 1981 Mazda GLC vehicles'"—were "overbroad, excessively burdensome, and oppressive in that they seek information that is irrelevant to the issues raised by the pleadings and inquire into matters well beyond the material facts and issues in this case." 524 So. 2d 1021, 1022–24 (Fla. 1st DCA 1987). In so doing, the court acknowledged that the lower court had "departed from the essential requirements of the law" by, among other things, "failing

[10] Defendants reserve the right to rely upon their bioequivalence testing documents, which are included in the ANDA files produced as Core Discovery.

to limit … [discovery] with respect to … the nature of the collision with actually occurred[.]" *Id*. at 1024.

Similarly, in *Cardenas v. Dorel Juvenile Group, Inc.*, the parents of a child injured in an automobile accident filed a products liability suit against the manufacturer, claiming a "side impact"-related injury. *See* 230 F.R.D. 611, 614–615 (D. Kan. 2005). In discovery, the plaintiffs sought production of, among other documents, "static and dynamic testing documents for the Touriva 'for any purpose and under any type of test configuration other than a side impact.'" *Id*. at 630. The manufacturer objected, pointing to the fact that "Plaintiffs' claims are based on the alleged absence of side impact protection" and that, consequently, "documents relating to any testing of the Touriva other than for side impacts is not relevant and not likely lead to the discovery of admissible evidence." *Id*. at 631. The court agreed with the manufacturer's objection, explaining that it "fails to see how documents relating to testing *other than side impact testing* are relevant to this case[.]" *Id*. (emphasis in original).

As with the particular functional components in *Stipes*; the specific type of collision in *Mazda*; and the side impact-related defect in *Cardenas*, the nitrosamine impurities are the only alleged "defect" in the valsartan API, and the tests that would—potentially—have identified such impurities, the HPLC and GC impurity tests, are the only tests for which documentation is properly discoverable. "The discovery rules are designed to assist a party to prove a claim it reasonably believes to be viable *without discovery*, not to find out if it has any basis for a claim." *Micro Motion, Inc. v. Kane Steel Co, Inc*., 894 F.2d 1318, 1327 (Fed. Cir. 1990) (*citing Netto v. AMTRAK,* 863 F.2d 1210, 1216 (5th Cir. 1989); *MacKnight v. Leonard Morse Hosp.,* 828 F.2d 48, 52 (1st Cir. 1987); *Marshall v. Westinghouse Elec. Corp.*, 576 F.2d 588, 592 (5th Cir. 1978); *Hinton v. Entex, Inc.,* 93 F.R.D. 336, 337–38 (E.D. Tex. 1981); and *Isaac v. Shell Oil Co.*, 83 F.R.D. 428 (E.D. Mich. 1979)).

The fact that Plaintiffs have specifically alleged the presence of certain impurities in certain valsartan medications does not entitle them to *carte blanche* discovery of documents concerning all valsartan-related testing. The court should not permit Plaintiffs to abuse the discovery process by extrapolating the scope of relevancy in such a manner. Indeed, "[t]hat discovery might uncover evidence showing that plaintiff has a legitimate claim does not justify the discovery request." *Micro Motion*, 894 F.2d at 1327.

E. Health Risk Discovery Should be Limited to the Injuries Alleged in the Master and Short Form Complaints.

1. Facts Pertinent to This Argument

In their Master Complaint, the Personal Injury Plaintiffs allege that the specific injury they suffered was cancer. *See* Personal Injury Master Complaint at ¶ 394 ("As a result of Plaintiffs' ingestion of the VCDs, Plaintiffs developed and were diagnosed with cancer, which caused permanent and disabling injuries and/or death."). In the Short Form Complaints filed to date,

Personal Injury Plaintiffs overwhelmingly identify the following cancers as their injuries: liver, stomach, pancreatic, small intestine, kidney, colorectal, esophageal, colon, and bladder. The Short Form Complaints also identify a handful of additional injuries, including kidney and liver injuries.

2. Example Discovery Requests

Plaintiffs seek broad discovery relating to health risks. For example, in their First Set of Requests for Production to All API and Finished Dose Manufacturers, Plaintiffs include the following requests:

> REQUEST NO. 39: *Produce all documents with regard to evaluation by an employee of defendant or a third party, of the health risks of valsartan contamination.*
>
> REQUEST NO. 48: *Produce all documents and communications with regard to the health risks due to contamination of valsartan with any nitrosamine or other carcinogenic substance.*
>
> REQUEST NO. 49: *Produce all studies, data, or other scientific or medical information reviewed or considered by any employee with regard to the health risks due to contamination of valsartan with any nitrosamine or other carcinogenic substance.*

See also Requests No. 4(5)-(7), 4(13), 5(5)-(7), 5(13), 6(5)-(7), 6(13), 9, 10(5)-(7), 10(13), 40-41, 60-62, 83-84, 87.

Because the Complaints dictate the appropriate bounds of discovery, these requests and similar requests seeking broad production of health effects documents are proper only insofar as they are limited to information concerning the injuries alleged in the Complaints.

3. Argument and Citations to Authority

Plaintiffs request documents related to *any* valsartan health risk or defect, regardless of its relevance to Plaintiffs' alleged injuries or the alleged manufacturing defects in the Master Complaints and Short Form Complaints. These requests reach far beyond the scope of Rule 26(b), which allows discovery only of "nonprivileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b). "[W]hen a request for discovery is overly broad on its face or when relevancy is not readily apparent, the party seeking discovery has the burden to show the relevancy of the request." *Burleson*, 2014 WL 11514677, at *1; *accord Gregory*, 2016 WL 6122456, at *3; *Engers*, 2004 WL 5902865, at *7.

Here, the Personal Injury Plaintiffs have alleged a specific set of injuries: certain cancers and a small number of other related injuries. Any requests relating to health risks beyond these specifically-alleged injuries is facially overbroad and wholly irrelevant. Plaintiffs should not be afforded this opportunity to seek discovery wholly untethered to their allegations in an attempt to

increase the burden on Defendants and to fish for new information to increase their recoveries. "The discovery rules are designed to assist a party to prove a claim it reasonably believes to be viable *without discovery*, not to find out if it has any basis for the claim." *Micro Motion*, 894 F.2d at 1327 (emphasis in original). Plaintiffs "have no entitlement to discovery to develop new claims or defenses that are not already identified in the pleadings." *Engers*, 2004 WL 5902856, at *7 (quoting *Court Rules: Amendments to Fed.R.Civ.P.*, 192 F.R.D. 340, 389 (2000))

Plaintiffs' requests for documents relating to *any* health risks mirror requests that a District Court ruled overbroad in *Paul v. Holland America Line, Inc.*, No. 05-2016, 2006 WL 8454908, *3 (W.D. Wash. October 19, 2006). In *Paul,* plaintiffs alleged that they contracted echovirus on a cruise ship. During discovery, the *Paul* plaintiffs made a number of requests, including for "any and all document [relating to or referring to] any medical illness reported" by a passenger on the cruise. *Id.* at *1. The Court denied the plaintiffs' motion to compel, holding that this request was overbroad and irrelevant. *Id.* at *3. *See also United Oil Co., Inc. v. Parts Associates, Inc.*, 227 F.R.D. 404, 410 (D. Md. 2005) (holding that information about "heart disease as a result of exposure" are unrelated to what "the manufacturer knew or reasonably should have known about the effect of exposure to the liver"); *In re National Collegiate Athletic Ass'n*, 543 S.W.3d 487, 493-494 (Ct. App. Tex. 2018) (holding that a plaintiff's request for information for documents related to "head trauma" was overbroad because it would capture information about injuries unrelated to "brain injuries," which had been alleged by plaintiff).

Allowing Plaintiffs discovery of health effects beyond the narrow set of injuries alleged in complaints would take this case far afield from the allegations of the Complaints, and would fall outside the bounds of Rule 26. Such irrelevant discovery would be a prime example of getting "distracted by tangential issues," a result that Judge Kugler has repeatedly emphasized he was committed to avoiding. July 10, 2019 Tr. at 22; *see also* Aug. 14, 2019 Letter from Judge Kugler (Dkt. 183).

F. The Relevant Time Period for Discovery Should Be Limited to the Time Period During Which the Manufacturer Sold Valsartan into the U.S. for Commercial Use, with Limited Exception for Discovery Relating to Manufacturing.

Plaintiffs' Requests for Production generally seek documents from January 1, 2010 to present. *See* Exhibit A at 3. For certain topics, however, Plaintiffs seek documents extending back further in time. For example, for their requests relating to agreements, manufacturing, bioequivalence, and testing, Plaintiffs specify that the relevant time period "begin[s] on the date [Defendant] first began development of the process for manufacturing the API for valsartan, first submitted an ANDA or DMF to the FDA, or January 1, 2010, whichever is earliest." *Id.* at 6, 7, 8, 9.

Plaintiffs' expansive view of the relevant time period in this litigation threatens to bring about broad discovery wholly disproportionate to the needs of this case. Plaintiffs have issued 122 document requests, seeking documentation relating to unlimited injuries and unlimited contaminants, for all manufacturing facilities, for any drugs manufactured utilizing the production

of tetrazole rings or the use of the solvents used to produce valsartan API.[11] Allowing Plaintiffs to pursue such broad discovery of information spanning ten or more years threatens to mire this litigation in extraneous issues and needlessly prolong resolution of the cases.[12]

Such exceedingly broad discovery is particularly disproportionate to the needs of the case here, where the key facts are already known. This litigation arises out of an extensive investigation by the FDA. *See* Transfer Order at 1. The documents already produced as Core Discovery in the litigation contain key information about Defendants' manufacturing processes, testing methods, the discovery of NDMA and NDEA in their products, and the investigation into cause of the NDMA and NDEA impurities. Plaintiffs' efforts to obtain unbounded discovery going back *ten or more years in time* is wildly disproportionate to the needs of this case. Rather than allowing for such unfettered discovery, the Court should tailor discovery to the time periods during which documents relevant to Plaintiffs claims were likely to be generated.

1. ZHP

Rule 26(b) allows for discovery of information relevant to "any party's claim or defense." Fed. R. Civ. P. 26(b). Plaintiffs' claims are predicated on their purchase and/or consumption of valsartan in the United States and are based on allegations regarding a specific API manufacturing process. These allegations should generally define the limits of discovery to apply only to the time period where ZHP's valsartan could have been purchased or used by Plaintiffs in the United States. For discovery on ZHP's manufacture of valsartan, discovery should be limited to the period in which ZHP manufactured valsartan API for the U.S. market pursuant to the manufacturing process alleged in the Complaint.

ZHP has issued letters of authorization—which allow manufacturers to rely on ZHP's Drug Master File for valsartan API in the authorized party's ANDA for their own finished dose valsartan product—to a number of companies. *See* PRINSTON00008870. The first of these companies to

---

[11] During the Parties' November 4 meet and confer, Plaintiffs explained that they intended to pursue discovery relating to all of Defendants' drugs manufactured using the creation of a tetrazole ring as well as all drugs manufactured using solvents similar to those used to produce valsartan API.

[12] Document production in this litigation will not be a swift or simple process. There are six foreign manufacturers in this MDL. International document collection and production is not simple. For example, foreign defendants are bound by any regulations relating to electronic data in their home countries. Where, as here, a defendant is based in China, it must not only take the typical steps required for a thorough document production, but must also conduct an extra layer of review of its documents to ensure compliance with the Guarding of State Secrets Law. Law on Guarding State Secrets of the People's Republic of China 1988 as revised in 2010, Order No 6 of the President of the People's Republic of China.

receive FDA approval for their valsartan ANDA was Torrent Pharmaceuticals Ltd. The FDA approved Torrent's ANDA on January 5, 2015. ZHP has only sold finished dose valsartan in the United States through Solco Healthcare U.S. This product was not approved for sale in the United States until Prinston Pharmaceuticals Inc.'s ANDA was approved on June 9, 2015.[13] Prior to that date, no entity was legally authorized to use ZHP's valsartan API in their finished dose valsartan products for sale in the United States. Accordingly, discovery on ZHP should generally be limited to the period from January 1, 2015 to present.

ZHP acknowledges that discovery into the valsartan API manufacturing process in use at the time its API was recalled in July 2018 may properly extend beyond 2015. ZHP began utilizing a new process to manufacture valsartan API in 2013. That process change was proposed on November 27, 2011. *See* PRINSTON0074768. Accordingly, ZHP's position is that the relevant time period for which it should produce discovery into its valsartan API manufacturing process, specifically in responses to Requests for Production Nos. 19-29, 53, 87, 97 (to the extent these requests seek information regarding manufacturing), extends from November 27, 2011 to present. To apply this relevant time frame beginning November 27, 2011 to other requests beyond those specifically seeking documents relating to manufacturing would force ZHP to produce a large volume of documents bearing no relation to the Plaintiffs' theory—that the valsartan they purchased and/or consumed caused them injury *because the valsartan products contained NDMA and/or NDEA impurities resulting from a specific step in the valsartan API manufacturing process. See, e.g.,* Personal Injury Master Complaint (Dkt. 122) ¶ 167; Economic Loss Master Complaint (Dkt. 121) ¶ 327; Medical Monitoring Master Complaint (Dkt. 123) ¶ 289 (alleging that NDMA and NDEA are byproducts of the chemical reaction involving the solvent used to create the tetrazole ring found in Valsartan).[14]

[13] Prinston's finished dose valsartan hydrochlorothiazide product was later approved for sale in the U.S. on February 8, 2016.

[14] Further, extending the relevant time periods beyond those proposed by ZHP would require ZHP to produce, for example: (i) formal and informal agreements with regard to a host of topics, including quality assurance, risk assessment, and formulation, for product that was never sold in the U.S. and was made under a different manufacturing process than the process placed at issue in the Master Complaints (Request No. 6); (ii) "all versions of [ZHP's] labeling for valsartan," including that was never used in the U.S. market (Request No. 79); and (iii) "final and draft versions of all documents provided to consumers upon purchase of valsartan," including valsartan sold to non-U.S. ANDA holders and reflecting representations about product produced under a different manufacturing process than the one placed at issue in the Master Complaints (Request No. 82). Such materials are of no relevance to this litigation.

2. Teva

Rule 26(b) allows for discovery of information relevant to "any party's claim or defense." Fed. R. Civ. P. 26(b). Plaintiffs' claims are predicated on their purchase and/or consumption of valsartan-containing products in the United States. Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis LLC, Actavis Pharma, Inc., and Arrow Pharm (Malta) Ltd. (collectively, "the Teva Defendants") first sold valsartan-containing products in the United States in March 2013. Accordingly, the Teva Defendants object to providing discovery responses that significantly predate sales in the United States, and specifically seek to define the relevant time period for their purposes as January 1, 2013, through the present.

As discussed above in Section IV.C, the finished dose manufacturing process is not implicated by Plaintiffs' allegations other than to the extent such process encompasses testing of valsartan API. Therefore, finished dose manufacturing activities which predate sales of valsartan are irrelevant, with the limited potential exception of the testing of valsartan API. Insofar as the Court finds that testing of valsartan API which occurred at the finished dose manufacturing level to be discoverable, and subject to the Court's rulings on Defendants' other objections, the Teva Defendants are willing to produce responsive documents related to testing of any valsartan API which was incorporated into finished dose products sold in the United States. However, for all other discovery requests, the relevant time period should be limited to January 1, 2013, through the present, unless Plaintiffs can show good cause as to why such limitation is not proportional to the needs of the case with respect to a given request.

3. Torrent

Rule 26(b) allows for discovery of information relevant to "any party's claim or defense." Fed. R. Civ. P. 26(b). Plaintiffs' claims against Torrent Pharmaceuticals, Ltd. and Torrent Pharma, Inc. (collectively, "Torrent") are predicated on their purchase and/or consumption of valsartan-containing products in the United States. Accordingly, Torrent objects to providing discovery responses that significantly predate sales in the United States. Torrent first sold valsartan-containing products in the United States in April 2015, and thus specifically seek to define the relevant time period for their purposes as January 1, 2015, through the present.

4. Aurolife and Aurobindo USA

Rule 26(b) allows for discovery of information relevant to "any party's claim or defense." Fed. R. Civ. P. 26(b). Plaintiffs' claims are predicated on their purchase and/or consumption of valsartan-containing products in the United States. Defendants Aurolife Pharma LLC and Aurobindo Pharma USA, Inc. (hereinafter, respectively, "Aurolife" and "Aurobindo USA") sell three finished dose valsartan-containing products in the United States. The first of those to be approved for sale in the United States was Valsartan HCTZ. Aurolife's ANDA for Valsartan HCTZ was approved on March 21, 2013. Therefore, Aurolife and Aurobindo USA submit that

the relevant time period for their purposes should be defined as March 21, 2013 through the present.

5. Mylan

This litigation relates to the sale, purchase, and use of VCMs in the United States. The Mylan Defendants did not market VCMs in United States until September 21, 2012, when FDA approved ANDA 078020. As part of core discovery, the Mylan Defendants produced the ANDA files and DMF relating to the products allegedly at issue. As such, Plaintiffs already have access to documents relating to design and formulation predating market entry. The Mylan Defendants submit, therefore, that the relevant time period for ESI discovery should be September 21, 2012 to present.

G. Privilege Logs Should Be Produced In Accordance with the Agreed ESI Protocol.

When the Parties met and conferred on these "macro" discovery issues on November 4, the Parties agreed that privilege logs should be produced in accordance with the ESI Protocol (Dkt. 127).

H. Plaintiffs Should Bear the Cost of Translating any Foreign Language Documents.

During the Parties' November 4 meet and confer, the Parties agreed that each party would separately bears its own costs in connection with generating any translations it chooses to create.

.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

SAG
Enclosures

cc: Adam Slater, Esq. (*via email*, *for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email*, *for distribution to Defendants' Counsel*)
Lori G. Cohen, Esq. (*via email*)
Clem C. Trischler, Esq. (*via email*)